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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,398	07/27/2006	Myoung Woo Lee	Q96125	3357

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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12/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No. 10/587,398	Applicant(s) LEE ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-34 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 12-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-11,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/4/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 9/28/09 to claims 1-5, 7-13, 15-21, 23-32, and 34 have been entered. Claims 1-5 and 7-34 remain pending in the current application, of which claims 1-5, 9-11, 33, and 34 are being considered on their merits. Claims 7, 8, and 12-32 remain withdrawn from consideration at this time. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Objections

Claims 9 and 10 are objected to because of the following informalities: The word "forskolin" is misspelled at line 3 of each claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The amendments to claims 2 and 9 change the scope of the amounts of glucose and pyruvate by three orders of magnitude with inadequate basis for doing so.

Applicant alleges that the product information sheet for the medium employed in the working examples provides basis for the amendment, but the examiner disagrees. This information is not substantiated by declaration or other evidence that the medium described in the technical specification sheet from invitrogen.com is identical to the Gibco 12800-017 medium used in the disclosure. Even if the working example included a single value from each of the newly claimed ranges, the specification does not contemplate these entire ranges implicitly or explicitly. At page 9, lines 35-36, the specification indicates that the ranges of glucose and pyruvate concentrations may be 3500 to 5500 mg/mL and 50 to 200 mg/mL, respectively.

The amendment to claim 3 changes the scope of the amounts of SCF and EGF in the third medium from “10 to 100 mg/mL,” e.g., to “10 to 100 ng/mL.” There is no basis in the as-filed specification for these newly claimed ranges. While the working example includes a single value from each of the newly claimed ranges, the specification does not contemplate these entire ranges implicitly or explicitly. At page 11, line 5, the specification indicates that the ranges of SCF and EGF concentrations may be 10 to 100 mg/mL and 10 to 50 mg/mL, respectively.

The amendment to claim 4 changes the scope of the ranges of cells by a full order of magnitude with no proper basis in the as-filed specification. Applicant alleges in the remarks that Freshey equates 0.2cm^2 to 1mL, presumably referring to the first sentence at numeral 8: “Add medium ($0.1\text{-}0.2\text{ mL/cm}^2$), and disperse the cells...”. It is

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respectfully submitted that applicant has misinterpreted the teachings of Freshey. The method to which Freshey refers is a method for culturing cells in flat culture flasks, and the step to which applicant refers requires calculating a volume of medium to add for a given surface area of that flask. Volume and area are not equivalent; there is no simple conversion factor for a given area (cm^2) to volume. Volume is calculated by multiplying a given area by the appropriate depth (the third dimension), which may vary. Applicant is incorrect in asserting that Freshey provides such a conversion factor, given the laws of mathematics.

Applicant is required to cancel the new matter in response to this Office action.

Claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 requires, *inter alia*, culturing mononuclear cells isolated from bone marrow in a medium comprising "endothelial growth factor (EGF)" to yield "multipotent progenitor/stem cells." Claim 5 is drawn to the progenitor/stem cells *per se*. Claim 9 is drawn to a method of using the progenitor/stem cells.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the

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state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims appear to be drawn at least in part to stem cells and methods of making the same. By definition, stem cells are multipotent and they have the potential for self-replication; see Reid et al. (2000, U.S. Patent 6,069,005; reference A) at column 1, lines 37-48. In order to be considered a stem cell, therefore, a given cell must be shown to have the capacity of self-replication. Multipotent progenitor cells, by contrast, have no such property. There is no evidence in the specification that the cells of the invention were examined for their ability to self-replicate. Such evidence is required for applicants to claim stem cells or methods of making or using them.

Furthermore, the specification provides insufficient guidance that the skilled artisan could have carried out the claimed method using the disclosure in view of the art. Claims 1 and 5 recite the term “endothelial growth factor (EGF),” but the acronym “EGF” is accepted in the art as an abbreviation for epidermal growth factor. There is no molecule accepted by the art as having the name “endothelial growth factor,” but the art does recognize vascular endothelial growth factor (VEGF). See Isner (1997, U.S. Patent 5,652,225; reference B) at column 3, lines 40-53. In light of the art, it is not clear which growth factor is necessary in the third medium, and since the field of art is

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nascent, guidance from applicants is necessary. The specification discloses the same queried phrase at page 3, line 37, so it cannot clarify the issue.

Because claims 2-4, 9-11, 33, and 34 depend variously from claims 1 and 5 and do not clarify this enablement issue, they must also be rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite the term “endothelial growth factor (EGF),” which is confusing because the acronym “EGF” is accepted in the art as an abbreviation for epidermal growth factor. There is no molecule accepted by the art as having the name “endothelial growth factor,” but the art does recognize vascular endothelial growth factor (VEGF). See Isner (1997, U.S. Patent 5,652,225; reference B) at column 3, lines 40-53. In light of the art, it is not clear which growth factor is necessary in the third medium. The specification discloses the same queried phrase at page 3, line 37, so it cannot clarify the issue. Clarification is required.

Claims 1, 5, and 33 recite the term "stem/progenitor cell," which is confusing because it is not clear whether the phrase is intended to be interpreted as “stem or progenitor cell” or as “stem cell, which is also a progenitor cell.” Clarification is required.

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Because claims 2-4, 9-11, 33, and 34 depend variously from indefinite claims 1 and 5 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 34 is confusing in that it is drawn to a composition “which is administered into a subject in need thereof.” It is not clear whether the claim is intended to recite a composition or a method of administration. Clarification is required. The claim should clearly indicate that a composition is being described and particularly describe the composition’s structural properties. Applicant is reminded that a method of use is already under examination (claim 9), so amending claim 34 to recite a method of administration will result in the claim being withdrawn from consideration until the time of allowance.

No claims are allowed.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651